

SAS:sas 04/15/04 269908
PATENT

Attorney Reference Number 899-61868
Application Number 10/019,165

Remarks

Claims 11-22, 27-36 and 41-46 are withdrawn from consideration. Claims 41-43 and 46 are canceled herein. Claims 1-4, 7, 44-45 and 46 are amended herein. Claims 41-43 and 46 are canceled herein. Following entry of this amendment, claims 1-10, 37-40, 44 and 45 are pending.

Support for the amendments of claims 1-3, 41-43 and 46 can be found throughout the specification, for example on page 12, lines 24-29. Claim 1 has also been amended to incorporate a limitation of original claim 4. Support for this amendment of claim 1 also can be found throughout the specification, for example on page 9, lines 8-24. Claim 1 is also amended to correct form. Support for the amendment of claim 4 can also be found throughout the specification, such as on page 9, lines 8-24. Support for the amendment of claims 7 and 44 can be found throughout the specification, such as on page 9, lines 24-28 and on page 11, line 23 to page 13, line 3. Claims 44 and 45 are amended to correct dependency.

Applicant believes no new matter is added by these amendments. Reconsideration of the subject application is respectfully requested.

Summary of Examiner Interview

Applicant thanks Examiner Lankford for the helpful telephone conference of April 13, 2004 with the undersigned representative, wherein the outstanding rejections were discussed. Amendments to the claims to overcome all of the outstanding rejections were also discussed. These amendments are set forth herein.

If any additional matters remain to be discussed before a Notice of Allowance is issued, the Applicant respectfully requests that the Examiner contact the undersigned, at the telephone number listed below, to initiate a telephone interview.

SAS:sas 04/15/04 269908
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Restriction Requirement

The restriction requirement has been made final. Applicant reserves the right to petition the restriction requirement.

Rejections under 35 U.S.C. § 102

Claims 1-3 and 6-10 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by EP 0730849 (hereinafter the '849 patent) and U.S. Patent 5,876,708 (hereinafter the '708 patent). Applicant respectfully traverses this rejection as applied to the amended claims.

The '849 patent discloses an arteriovenous bypass grafting procedure in which a vein segment is implanted into the arterial circulation of a mammalian subject, and a non-porous stent is provided around the grafted vein. This graft is used to bypass stenotic coronary arteries.

The '849 patent teaches that vein segments can be used to bypass an obstructed artery, and does not teach, nor does it render obvious, the use of vascular tissue to treat subjects deficient in hematopoiesis. As noted in the Office action, the '849 patent does not disclose, nor render obvious, the use of a transplant to enhance hematopoiesis, let alone the treatment of subjects deficient for hematopoiesis. Thus, the '849 patent does not anticipate, nor render obvious, claims 1-10 and 37-40 as amended. Reconsideration and withdrawal of the rejection are respectfully requested.

The '078 patent teaches the use of organ transplants, and teaches that a short course of an immunosuppressant can be used to induce tolerance to a graft. It should be noted that the graft is an allograft (see column 4), specifically a liver or a kidney graft (see line 65), or a heart, lung

SAS:sas 04/15/04 269908
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bone, skeletal matrix, skin, intestines, endocrine gland, or progenitor cells of various types (see column 16, lines 46-51). Although the '078 patent discloses that the graft can be a tissue graft or an organ, the use of isolated blood vessels is not specifically disclosed. Moreover, the methods disclosed in the '078 patent are designed to promote tolerance to the graft, and not to enhance hematopoiesis. Indeed, the methods disclosed in the '078 patent are designed to *prevent* the formation of T and B cells.

The '078 patent does not disclose or suggest the transplantation of an isolated adult vascular tissue into a subject deficient for hematopoiesis, in order to promote hematopoiesis in this subject. Thus, the '078 patent does not disclose, nor render obvious, claims 1-10 and 37-40 as amended. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-10 and 37-40 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly the specification is not enabling for transplanting any and all vascular tissue in order produce hematopoiesis. Applicant respectfully disagrees with this assertion.

The use of a therapeutically effective amount of an isolated adult vascular tissue is disclosed in the specification (see for example, page 8, lines 31). As disclosed in the specification, vascular tissue includes the arteries, veins and capillaries. Examples of vascular tissue are set forth in the specification on page 9, lines 24-30.

Moreover, experiments are described wherein hematopoiesis was enhanced in a subject deficient for hematopoiesis (for example, irradiated mice, see Example 1-6, pages 12-15). In these experiments, a therapeutically effective amount of an artery (the thoracic aorta) or a vein (the vena cava) were used to enhance hematopoiesis. Mice transplanted with either a

SAS:sas 04/15/04 269908
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therapeutically effective amount of the artery or the vein had colony forming units in their spleens, showed dramatically increased survival, and exhibited multi-lineage reconstitution. Thus, the specification is fully enabling for the use of a therapeutically effective amount of either an artery or a vein to enhance hematopoiesis in subjects deficient for hematopoiesis.

In addition, examples are disclosed wherein blood vessels, such as capillaries, are used to enhance hematopoiesis in subjects deficient for hematopoiesis (for example, irradiated mice, see Example 7, page 16, lines 5-27). Irradiated mice transplanted with other vessels also exhibited enhanced survival and hematopoietic reconstitution.

As discussed with Examiner Lankford, the Applicant has conducted further experiments wherein a therapeutically effective amount of a blood vessel was transplanted intraperitoneally into lethally irradiated mice to enhance hematopoiesis. These methods are disclosed in the specification (see, for example, page 9, lines 31-35, and page 10, lines 24-26). A declaration can be submitted to present these experimental results, if the Examiner believes it would expedite prosecution of the present application.

The Applicant submits that the specification is fully enabling for the use of vascular tissue, including arteries, veins, and smaller vessels, to enhance hematopoiesis in subjects deficient for hematopoiesis. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-10 and 37-40 are rejected as allegedly missing essentially elements. The Office action alleges that there must be additional elements besides vascular tissue that are essential for enhancing hematopoiesis. Applicant respectfully disagrees with this assertion.

SAS:sas 04/15/04 269908
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As discussed with Examiner Lankford, the disclosure of the present application teaches that vascular tissue can be used to enhance hematopoiesis. Although other elements such as growth factors or cytokines can be included, these are not essential to the process. Indeed, the Examples describe experiments in which hematopoiesis was enhanced in irradiated mice by the transplantation of a portion of an artery or a vein alone (without the use of supplemental growth factors or cytokines, see Examples 1-7).

Thus, the Applicant submits that the claims, as pending, set forth the essential steps of the process. Reconsideration and withdrawal of the rejection are respectfully requested.

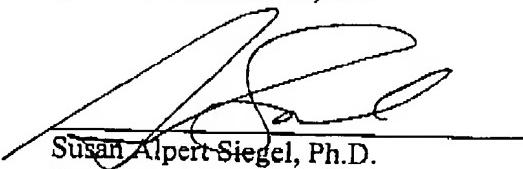
Conclusion

Applicant believes the pending claims are now in condition for allowance. If any matters remain to be addressed before a Notice of Allowance is issued, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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